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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/758,237 | 01/15/2004 | Perry B. Hackett | 3021.15US02 | 5310 |

62274 7590 04/24/2008

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| EXAMINER | |
|---|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 04/24/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Continuation of 5. Applicant's reply has overcome the following rejection(s):**

Rejection of claims 23 and 26 under 35 USC 112, second paragraph, is withdrawn in view of the claim amendments. In addition, receipt of statements that the paper copy and CRF submitted 13 February 2007 and 21 May 2007 are the same and include no new matter is acknowledged. However, the Examiner can find no amendment specifically directing entry of the paper copy of the sequence listing into the specification. (See page 3 of the 13 February 2008 Office Action.)

**Continuation of 11. does NOT place the application in condition for allowance because:**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 19-21, 23, 27, 28, 31-35, 37, 41-43, 85-87, 90-94 and 102 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Hackett et al. (1998) WO 98/40510 in view of Chung et al. (*supra*). This rejection is maintained for the reasons set forth in the previous Office Actions and herein below in the response to Applicant's arguments.

Claims 1, 25 and 26 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Hackett et al. (*supra*) in view of Chung et al. (*supra*) as applied to claim 1 above and further in view of Pope et al. (1997) *Eur. J. Cancer* 33:1005-1016. This rejection is maintained for the reasons set forth in the previous Office Actions and herein below in the response to Applicant's arguments.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hackett et al. (*supra*) in view of Chung et al. (*supra*), as applied to claim 1, and further in view of Wooddell et al. (*supra*). This rejection is maintained for the reasons set forth in the previous Office Actions and herein below in the response to Applicant's arguments.

*Response to Arguments*

In response to the *prima facie* rejection and arguments of record, Applicant submits that because the Sleeping Beauty transposase functions by bringing the ITRs into closer proximity insulator process that also brings ITRs into closer proximity would compete with the function of the Sleeping Beauty transposase and would be expected by the ordinary artisan to reduce the

transposase's activity, as by competitive inhibition. Applicant concludes therefore, that the prior art leads the artisan away from using insulators.

This argument has been fully considered but is not deemed persuasive. Applicant's conclusion that an insulator necessarily "competes" with sleeping beauty transposase because it comprises a looping mechanism is unfounded. Clearly, a DNA comprising one loop is not prohibited from comprising a second loop, any more than a piece of string that crosses once is prohibited from crossing a second time. Therefore, one would not view an insulator element that acts by forming a loop in DNA as competitive with a transposase that also acts by forming a loop in DNA. In view of this, there is no basis for concluding that an insulator element would so completely interfere with the functioning of sleeping beauty transposase that one of skill in the art would not be motivated to include insulator elements in the transposon of Hackett et al., particularly in view of the teachings of Chung et al. expressing the many advantages of including insulator elements in nucleic acids to be used in the construction of transgenic animals and cells as contemplated by Hackett et al. Therefore, one of skill in the art would not, in fact, view evidence that the functioning of both the insulator element and sleeping beauty transposase involve a looping mechanism as a teaching away from using them in combination in view of the record as a whole.

The remainder of Applicant's arguments is based on evidence provided after final rejection without a showing of good and sufficient reason as to why the evidence is necessary and was not earlier presented. As the evidence has not been entered, these arguments are moot.

/Daniel M Sullivan/
Primary Examiner, Art Unit 1636